May 24, 2019

HOBIT NEWS

Hyperbaric Oxygen Brain Injury Treatment Trial Newsletter

Reminders

+NETT/SIREN Study Coordinator Call

June 4th at 1pm ET

+Virtual Investigator Meeting

June 11th 11:00am-12:30pm ET

June 13th 3:00pm-4:30pm ET

+GOSE Quarterly Meeting

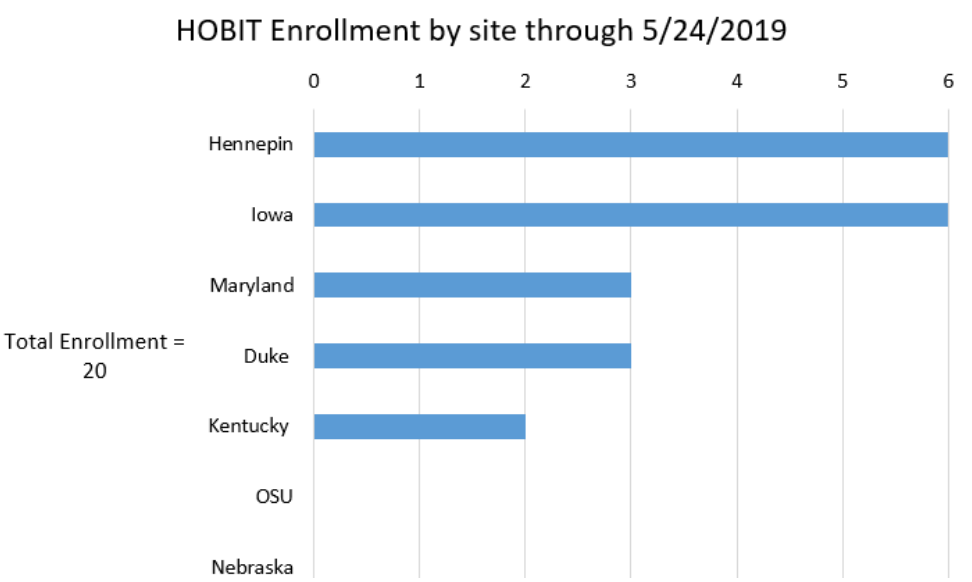
June 12th 12:00pm ET

Iowa, Hennepin & Duke — Screening Logs Complete

Great job to Iowa, Hennepin, and Duke for recently completing screening logs!

Kentucky & Iowa—GOSE Complete

Nice work by Kentucky & Iowa on recently completing 180 day GOSE assessments!



HOBIT Updates

MOP Updates

Update to section 3.6.1 page 16 (new language added)

In order to ensure blinding, the GOSE assessor should not view the subject's medical records or consult with study coordinators/personnel regarding the GOSE assessments.

Update to section 3.2 page 12 (new language added)

Subjects with extensive skull fractures with associated extensive pneumocephalus should be excluded from the trial. Subjects with skull fractures without extensive pneumocephalus (for example: a small amount of air under an open fracture / in the subarachnoid space) may be enrolled, however, they should be monitored closely for the development of significant pneumocephalus or significant increase in the size of a previously small pneumocephalus. If these changes occur, HBO dives should be held until pneumocephalus resolves. Call the HOBIT PI line if you have additional questions regarding this.

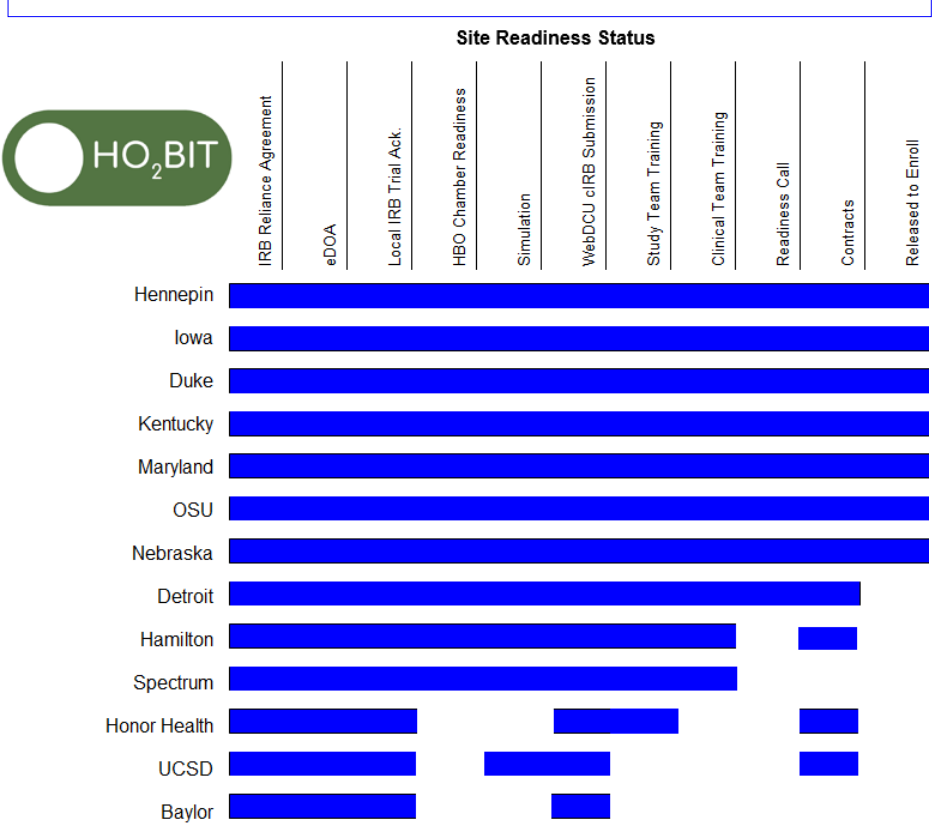
FAQ

A new FAQ has been added to the HOBIT website:

Q: Which GCS should be used to determine eligibility for HOBIT?
A: The GCS used to determine eligibility is not necessarily the initial GCS or the lowest GCS but the most RELIABLE GCS. The GCS exam should be performed after resuscitation, off sedatives and paralytics and closest to the time of enrollment. This is because patients frequently improve or deteriorate neurologically during the first hours following injury. Alcohol and recreational drugs may suppress neurological function, resulting in a low GCS which may improve quickly. Therefore it is particularly important especially in patients with an initial GCS of 7 and 8 to obtain a repeat GCS close to enrollment. Do not hesitate to call the PI hotline if you have questions regarding eligibility.

Dive Log Version 4

An updated version of the dive log is now available in the HOBIT toolbox, under, "Chamber Resources". Instructions for completing this form are on page 2 of the log.

Monthly Monitoring Log

We want to remind study teams to conduct monthly follow-up phone calls with enrolled subjects/LAR during their time of enrollment for the first 6 months post-randomization. These calls are essential to maintaining contact with subjects/LAR and decreasing the likelihood of "loss to follow-up" at the 6-month visit. A log of all calls is documented in the Monthly Follow-up Log in WebDCU under the **Study Progress** tab. More instructions are available in the MOP on page 17 section 3.6.1.